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Development of biobanking in Russia: legal aspect

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INTRODUCTION

The circle of "**interested parties**" in the full functioning of biobanks:

- ***medical and pharmaceutical industries*** (biobanks, undoubtedly, are one of the basic components of personalized medicine: they allow large-scale population studies, search for new biomarkers, etc.; samples of human biological materials are an integral part of fundamental developments and a key component of all programs for creation of medicines);
- ***research and educational organizations, etc.***

The presence of information registers can be considered as part of a broader structure - a biobank, while among the subjects of this type of activity are distinguished:

- ***organizations storing biosamples and information at the same time,***
- ***exclusively for operators of information systems.***

THE CONCEPT OF BIOBANKS



Main doctrinal approaches:

- “**subject**” (biobanks are organizations with special legal personality, etc.),
- “**object**” (biobanks are objects of rights).

Russian legislation also considers biobanks from two perspectives:

- **as subjects** of circulation of biomedical cell products (section III of the order of the Ministry of Health of the Russian Federation dated October 20, 2017 No. 842n "On approval of requirements for the organization and operation of biobanks and rules for storing biological material ...");
- **as objects** of civil turnover.

CONCLUSIONS AND OFFERS:

- A. It is proposed to consider a biobank as a **complex object of legal relations**, including:
 - a set of **biomaterials** (biosamples);
 - **information** that is collected on their basis (they can form the content of an information base or a register of relevant data).
- B. **The legal regime** of such a complex (complex) object **will consist of the regimes of its constituent elements provided for by the law.**
- C. **Legal entities that own biobanks can not only store and research biomaterials, but also carry out other activities** (scientific, educational, medical, both directly related and not related to the presence of relevant collections).

LEGAL REGULATION IN THE SPHERE OF BIOBANKING



There are **two key approaches to the legal regulation** of relations emerging in this area:

- Adoption of special acts dedicated exclusively to biobanks;
- inclusion of relevant provisions in regulations ***covering a wider range of relationships arising*** in connection with the conduct of genetic research.

Russian legal regulation is fragmented, does not contain the necessary definitions, and allows for conceptual ambiguity (this prevents relevant research and data exchange); at the moment, only the rules for the transportation and storage of biomaterials have been established as a function of biobanks (which is clearly not enough).

CONCLUSIONS AND OFFERS:

- ▶ The creation of a regulatory framework in this area must be approached systematically: **on the basis of a single legal conceptual apparatus, it is appropriate to formulate general provisions regarding the status of entities that have biobanks, and the regime of bio-samples and information obtained on their basis.**
- ▶ At the same time, **it is quite permissible to issue both a separate regulatory legal act and the implementation of coordinated adjustments to an already existing regulatory framework.**
 - ▶ In general, the concept of publication as a **basic special law on biobanks** deserves support, in which they should find the confirmation of their legal regime as an object of rights (and not the legal status of a biobank as a subject!), As well as rules for organizations that are in charge of biobanks.

TYPES OF BIOBANKS:



- ▶ **Depending on the type of storage objects:**

- universal;

- specialized (collections of dissimilar or homogeneous materials).

- ▶ **By appointment:**

- to accompany scientific research;

- for drug development,

- contributing to the work of law enforcement agencies, etc.

- ▶ **By belonging to any area (organization) and source of funding:**

- at educational institutions;

- at scientific institutions;

- at medical institutions, etc.

- ▶ **By the scale (territory) of operation:**

- local;

- regional;

- national;

- international.

- ▶ **An autonomous place** is occupied by population biobanks that conduct a comprehensive survey of various population groups to determine the profile of biomarkers inherent in a given population, genetic bases and the incidence of diseases.

CONCLUSIONS AND OFFERS:

Separate attention from the point of view of civil turnover deserves the division of biobanks into **commercial and non-commercial**. The doctrine expresses a reasonable distrust of commercial structures, which led to the establishment in some countries (unlike Russia) of a ban on the commercial segment of the economy to engage in biobanking (Italy, France, etc.). We believe that the creation of commercial biobanks should not be completely ruled out.

It is necessary to overcome the fragmentation of biobanks and build a coordinated system.



FINAL PROVISIONS:

- ▶ research and development should become a priority goal of using bio-samples collections and information obtained on their basis; however, in relation to them, a special procedure for third-party access to the specified materials and information should be introduced, which, in turn, should be largely determined by the data regime and their personalization;
 - ▶ it is possible to introduce different types of consent of their holders for access to such information, different in nature, volume and content: it can be broad, open, etc. however, in any case, mechanisms should be developed to ensure the quality of the research, the ability to monitor it, adherence to ethical rules during its conduct and the awareness of the results;
 - ▶ within the framework of the general regime for the use of biomaterials and genetic information, it is necessary to highlight the procedure of cross-border exchange, which is of particular importance for the full functioning of biobanks, and in need of an autonomous unified, in terms of international rules, legal regulation;
- ▶ the creation of commercial biobanks should not be ruled out: their functioning is quite permissible in cases and limits established by law.